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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,511	11/30/1999	KAORU ARAI	P18214	7711

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER
MAYES, MELVIN C

ART UNIT	PAPER NUMBER
1734	23

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-23

Office Action Summary	Application No.	Applicant(s)	
	09/450,511	ARAI ET AL.	
	Examiner	Art Unit	
	Melvin Curtis Mayes	1734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,7,9,10 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,7,9,10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

(1)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2003 has been entered.

Claim Rejections - 35 USC § 103

(2)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(3)

Claims 1, 4, 6, 7, 9 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. 5,645,596 in view of Kim et al. 5,980,572 and Brosnahan et al., and further in view of Ogawa et al., Saita et al. 5,128,169, Shimp et al. and "Modern Ceramic Engineering."

Kim et al. '596 discloses a method of making a ceramic vertebrae prosthesis comprising: providing a dried dense material to correspond to the center portion used to contribute to an increase in strength, providing a dried porous material to correspond to the circumferential portion to contribute to accelerated adhesion of the prosthesis to vertebra bodies; adhering the dried dense material to the dried porous material by an apatite slurry; and heating the assembly.

The ceramic is preferably a calcium phosphate ceramic and is advantageously calcium phosphate compound of Ca/P ratio of 1.0 to 2.0 such as hydroxyapatite. The hydroxyapatite is made by a wet process using phosphate salt and calcium salt. Kim et al. disclose heating hydroxyapatite at 1000-1200°C to obtain a final product (col. 4, lines 18-38, 50-52, col. 5, lines 1-6 and 13-26). Kim et al. disclose that hydroxyapatite slurry can be prepared by a wet composition process using a phosphate salt and calcium salt but does not specifically disclose that the apatite slurry used to adhere the dried materials is synthesized by merely adding a phosphoric compound to a calcium compound slurry or is the same calcium phosphate compound as that of the dense and porous material. Kim discloses bonding a dense center portion to a porous portion but does not disclose bonding two porous portions.

Kim et al. '572 teach that in an artificial spine made of a porous ceramic portion and a core portion, the porous ceramic portion preferably has a porosity of 40-70% so that bone union can be accelerated as a function of permeation of bone tissue into the pores and the core portion may be formed of a dense or porous ceramic material (col. 3, lines 12-27).

Brosnahan et al. teach that in a vertebrae implant having a first portion of relatively high porosity to facilitate rapid bone ingrowth and a second portion having relatively low porosity for sufficient strength, the porosity of the second portion is less than 40% (col. 6, lines 2-30).

Ogawa et al. teach that hydroxyapatite can be synthesized by various known methods including a wet method in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution and a dry method in which phosphoric acid compound is reacted with a calcium compound under high temperatures. Ogawa

et al. teach making a hydroxyapatite slurry by dropwise adding a phosphoric acid solution to a calcium hydroxide slurry (col. 3, lines 31-52, col. 6, lines 32-40).

Saita et al. teach that for forming a hydroxyapatite coating onto a substrate, hydroxyapatite prepared by a conventional method, such as wet process or dry process, and teaches that the wet process is preferable because a product having fine particle size can easily be obtained and the product of the wet process is preferably used without drying after filtering and washing with water because undesirable production of agglomerates is inhibited. Saita et al. further teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1 μm when measured by a sedimentation method (col. 2, lines 35-45).

Shimp et al. teach that binders may interfere with the sintering process of hydroxyapatite, even if organic binders which leave no mineral residue upon firing are used (col. 1, lines 40-43).

Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth and grain growth in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination (pgs. 520-522).

It would have been obvious to one of ordinary skill in the art to have modified the method of Kim et al. '596 for making a ceramic vertebrae prosthesis by providing the center (core) portion also as a porous portion, as Kim et al. '572 teach that in an artificial spine made of a porous ceramic portion and a core portion, the core portion may be formed of a dense or porous ceramic material. Providing the core portion as a porous portion having a porosity within the

range of 15-70%, as claimed, would have been obvious to one of ordinary skill in the art, as Brosnahan et al. teach that in a vertebrae implant having a first portion of relatively high porosity to facilitate rapid bone ingrowth and a second portion having relatively low porosity for sufficient strength, the porosity of the second portion is less than 40%. Providing the porous portion for bone ingrowth of porosity with the range of 15-70%, as claimed, would have been obvious to one of ordinary skill in the art, as porosity of 40-70% is taught by Kim et al. '572 as preferable so that bone union can be accelerated as a function of permeation of bone tissue into the pores. Providing a center portion of porosity less than 40% for sufficient strength and circumferential portion of porosity of 40-70% for bone ingrowth, would have been obvious to one of ordinary skill in the art, as taught by Kim et al. '572 and Brosnahan et al.

It would have been obvious to one of ordinary skill in the art to have further modified the method of Kim et al. '596 by adhering the dried porous center portion and dried porous circumferential portion of hydroxyapatite by an apatite (hydroxyapatite) slurry prior to heating (sintering) in the method of Kim et al. using a slurry prepared by adding a phosphoric compound to a calcium compound slurry, as Ogawa et al. teach that the wet method (in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution) and the dry method are known methods of making a hydroxyapatite slurry, and Saita et al. teach that for forming a hydroxyapatite coating onto a substrate, hydroxyapatite prepared by a wet process is preferable because a product having fine particle size can easily be obtained. Using a slurry of hydroxyapatite particles prepared by a wet process for coating one or both of the dried materials of hydroxyapatite for adhering the materials would have been obvious to one of ordinary skill in the art as preferable for easily providing fine particle size needed for

providing a coating, as taught by Saita et al. Using a hydroxyapatite slurry prepared by the wet method would have been obvious to one of ordinary skill in the art because preparing hydroxyapatite slurry by the wet method is well known in the art, as taught by Kim et al., Ogawa et al., and Saita et al. Using hydroxyapatite slurry to adhere hydroxyapatite parts would have been obvious to one of ordinary skill in the art to provide the same material throughout the prosthesis made of the bonded parts.

Using a hydroxyapatite slurry prepared without drying the hydroxyapatite after forming by the wet process, and thus synthesized by merely adding a phosphoric compound to a calcium compound slurry as claimed in Claim 1, would have been obvious to one of ordinary skill in the art as Saita et al. to inhibit the undesirable production of agglomerates. Further, using a hydroxyapatite slurry prepared in the absence of organic components, as claimed in Claim 19, such as organic binder, for coating one or both of the dried materials for adhering the materials would have been obvious to one of ordinary skill in the art, as taught by Shimp et al. to prevent interference with the sintering process of hydroxyapatite.

By heating at 1000-1200°C to obtain a final product, as disclosed by Kim et al., the particles of the slurry fuse and grow during the sintering of the dried dense material and dried porous material, as Modern Ceramic Engineering teaches that sintering of ceramic comprises stages including an initial stage of particle rearrangement and neck formation at the contact point between particles, an intermediate stage of neck growth (i.e. fusing of particles) and grain growth, in which a particle begins to grow while the adjacent particle is consumed, and a final stage of much grain growth with porosity elimination.

Further, it would have been obvious to one of ordinary skill in the art to have prepared the slurry to have primary particles of average grain size in the range of 0.1 to 1 μm, and thus including the range of 0.05 to 0.5 μm as claimed in Claim 10, as Saita et al. teach that the particle size of the primary flocculated particles of hydroxyapatite prepared by the wet process is 0.1 to 1 μm when measured by a sedimentation method.

In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the combination of Kim et al., Ogawa et al., Saita et al., Shimp et al. and "Modern Ceramic Engineering," such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also In re Thorpe, 227 USPQ 964 (CAFC 1985).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

(4)

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of JP 2-225382.

JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products. JP '382 also teaches that the apatite is provided such that it is 5 to 40 wt% of an aqueous solution used for a bonding material (Abstract).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the amount of apatite in the bonding slurry in an amount in the range of 5 to 40wt%, and thus encompassing the range of 0.1 to 20vol% as claimed in Claim 9, as taught by JP '382 as the amount of apatite in an aqueous solution for a bonding material.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing particles of average grain size in the range of 0.1 to 15 microns in the slurry, and thus 0.05 to 0.5 microns as claimed in Claim 10, as taught by JP '382 as the average particle size of apatite suitable for applying between apatite products for bonding the products.

Response to Arguments

(5)

Applicant's arguments filed May 12, 2003 have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1 and 19 have been considered but are moot in view of the new ground(s) of rejection, applied because of the amendment to the claims. While Kim et al. discloses bonding a dense portion to a porous portion for a vertebrae implant, Kim et al. '572 and Brosnahan et al. clearly teach that both portions of such an implant can be porous, the porosity of the portion used to provide strength to the implant limited to less than 40% for sufficient strength.

The references Ogawa et al and Saita et al. reinforce the disclosure of Kim et al. '596 of how hydroxyapatite is synthesized by the wet process and how a hydroxyapatite slurry is formed, Saita et al. being particularly important because it suggests that to use hydroxyapatite for coating onto a substrate (which is how the apatite slurry of Kim et al. needs to be used between the dried parts) hydroxyapatite prepared by the conventional wet process is used as is without any other processing such as drying after filtering and washing with water.

With respect to no organic components in the slurry used for adhering, because apatite slurry is made by a wet composition process using phosphate salt and calcium salt, there is thus no organic components in the slurry. Shimp was cited because the reference suggests that binders may interfere with the sintering process of hydroxyapatite, even if organic binders which leave no mineral residue upon firing are used. This is further suggestion not to include organic in the slurry, nor in the parts to be bonded. There is no mention in Kim et al. of even using any kind of

binder to make the dense and porous parts to be bonded. JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products, encompassing the range of Claim 10.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The references as combined teach or suggest that it would have been obvious to one of ordinary skill to form a bone implant by bonding two porous hydroxyapatite portions of different porosity using a hydroxyapatite slurry.

Conclusion

(6)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin Curtis Mayes whose telephone number is 703-308-1977. The examiner can normally be reached on Mon-Fri 7:00 AM - 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 703-308-3853. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Melvin Curtis Mayes
Primary Examiner
Art Unit 1734

MCM
August 1, 2003